22 June 2023
EMA/424777/2023
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): tadalafil

Procedure No. EMEA/H/C/PSUSA/00002841/202210

Period covered by the PSUR:
14/10/2019 To: 14/10/2022

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for tadalafil, the scientific conclusions of the CHMP are as follows:

In view of available data on serous central chorioretinopathy from the literature and spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between tadalafil and central serous chorioretinopathy is at least a reasonable possibility. The PRAC concluded that the product information of products containing tadalafil should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for tadalafil the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tadalafil is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation(s) should be varied.